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| APPLICATION NO. | FILING D | DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|------------|------|----------------------|---------------------|------------------|--|
| 09/967,263 | 09/28/2001 | | Timothy O'Brien | D6415 | 5220 | |
| 7590 04/13/2006 | | | | EXAMINER | | |
| Benjamin Aaron Adler ADLER & ASSOCIATES | | | | UNGAR, SUSAN NMN | | |
| 8011 Candle La | | | ART UNIT | PAPER NUMBER | | |
| Houston, TX 77071 | | | 1642 | | | |

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | | |
|-----------------|----------------|---|--|
| 09/967,263 | O'BRIEN ET AL. | | |
| Examiner | Art Unit | _ | |
| Susan Ungar | 1642 | | |

| | | Susan Ungar | 1642 | |
|----------------------------|--|--|--|--|
| | The MAILING DATE of this communication appe | ars on the cover sheet wit | h the correspondence ac | dress |
| THE | REPLY FILED <u>02 December 2005</u> FAILS TO PLACE THIS | S APPLICATION IN CONDIT | ION FOR ALLOWANCE. | |
| | The reply was filed after a final rejection, but prior to or on this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a No a Request for Continued Examination (RCE) in compliance time periods: | wing replies: (1) an amendm tice of Appeal (with appeal f ce with 37 CFR 1.114. The re | ent, affidavit, or other evid ee) in compliance with 37 | ence, which CFR 41.31; or (3) |
| | The period for reply expiresmonths from the mailing | | | |
| b) | no event, however, will the statutory period for reply expire la Examiner Note: If box 1 is checked, check either box (a) or TWO MONTHS OF THE FINAL REJECTION. See MPEP 7 | ater than SIX MONTHS from the (b). ONLY CHECK BOX (b) WH 06.07(f). | e mailing date of the final reje EN THE FIRST REPLY WAS | ction. FILED WITHIN |
| have bunder set for may re | sions of time may be obtained under 37 CFR 1.136(a). The date seen filed is the date for purposes of determining the period of ex 37 CFR 1.17(a) is calculated from: (1) the expiration date of the sthin (b) above, if checked. Any reply received by the Office latereduce any earned patent term adjustment. See 37 CFR 1.704(b) CE OF APPEAL | tension and the corresponding a shortened statutory period for re than three months after the ma | amount of the fee. The appro ply originally set in the final O | priate extension fee iffice action: or (2) as |
| | The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exte a Notice of Appeal has been filed, any reply must be filed IDMENTS | nsion thereof (37 CFR 41.37 | (e)), to avoid dismissal of | nths of the date of the appeal. Since |
| 3. 🛛 | The proposed amendment(s) filed after a final rejection, | but prior to the date of filing | a brief, will not be entered | because |
| | (a) They raise new issues that would require further co | nsideration and/or search (s | ee NOTE below); | |
| | (b) ☐ They raise the issue of new matter (see NOTE belo | w); | | |
| | (c) They are not deemed to place the application in befappeal; and/or | ter form for appeal by mater | ially reducing or simplifyin | g the issues for |
| | (d) \prod They present additional claims without canceling a ϵ | corresponding number of fin | ally rejected claims. | |
| | NOTE: See Continuation Sheet. (See 37 CFR 1.1 | 16 and 41.33(a)). | | |
| 4. 🔲 | The amendments are not in compliance with 37 CFR 1.13 | 21. See attached Notice of N | lon-Compliant Amendmer | it (PTOL-324). |
| | Applicant's reply has overcome the following rejection(s) | | • | , |
| | Newly proposed or amended claim(s) would be al non-allowable claim(s). | lowable if submitted in a sep | earate, timely filed amendr | nent canceling the |
| 7. 🗌 | For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is provided that the claim(s) is (or will be) as follows: Claim(s) allowed: none. | | will be entered and ar | explanation of |
| | Claim(s) objected to: <u>none</u> . Claim(s) rejected: <u>1 and 5</u> . | | | |
| | Claim(s) withdrawn from consideration: | | | |
| AFFIE | DAVIT OR OTHER EVIDENCE | | | |
| | The affidavit or other evidence filed after a final action, bu because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | t before or on the date of fili d sufficient reasons why the | ng a Notice of Appeal will gar a Notice of Appeal will gar affidavit or other evidence | not be entered is necessary and |
| | The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessar | vercome all rejections unde | r appeal and/or appellant t | ails to provide a |
| 10. 🗀 | The affidavit or other evidence is entered. An explanation | | | |
| | JEST FOR RECONSIDERATION/OTHER | | | |
| | The request for reconsideration has been considered bu See Continuation Sheet. | | | ance because: |
| | Note the attached Information Disclosure Statement(s). | (PTO/SB/08 or PTO-1449) P | aper No(s). | |
| 13 | Other: | | Susan Ungar | |
| | | | Primary Examine Art Unit: 1642 | r // ` |
| | | | | |

Continuation of 3. NOTE: The new issue raised is drawn to newly amended claim 1 which requires the limitation of the antibody being an IgG1k antibody which requires additional search and consideration.

Continuation of 11. does NOT place the application in condition for allowance because: As drawn to the rejection under 35 USC 103, If the amendment had been entered, the claims would still be rejected under 35 USC 103 for the reasons of record. Applicant reiterates the teachings of the prior art references and admits on the record that treatment with Herceptin alone effectively treated a subset of the patients disclosed, Applicant argues that if one were motivated to treat HER-2/neu over-expressing uterine serous papillary carcinoma with rhuMAb HER2 as claimed, one would be merely "trying" to arrive at the claimed invention due to the variability in the response rates to rhuMAB HER-2 alone and trying is not the standard for obviousness. The argument has been considered but has not been found persuasive because the references teach and applicant admits on the record that a subset of the patients were effectively treated with the instantly claimed invention.

As drawn to the rejection under 35 USC 112, first paragraph, Applicant argues that the amendment of the claims obviates the instant rejection. The arguments have been considered but clearly are most given that the amendment of the claims has not been entered..